DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
34357d
Central Region

Food and Drug Administratio
Waterview Corporate Center
10 Waterview Blvd., 3rd Floo
Parsippany, NJ 07054

Telephone (973) 526-6004

October 2, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Paul Kabaria
Owner & President
Nutra Med, Inc.
665 E. Lincoln Avenue
Rahway, New Jersey 07065

FILE NO.: 04-NWJ-01

Dear Mr. Kabaria:

On January 6 - 17, 2003 the U.S Food and Drug Administration conducted an inspection of your facility located at 665 E. Lincoln Ave., Rahway, New Jersey. During the inspection our investigator documented significant deviations from the Current Good Manufacturing Practices Regulations (cGMPs) Title 21, Code of Federal Regulations, Part 210 and 211, in conjunction with your firm's manufacture of Over-the-Counter (OTC) and Prescription drug products.

The inspection revealed that the drug products manufactured at your facility are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for their manufacture, processing, packing, or holding do not conform with cGMPs, to assure that such drug products meet the requirements of the Act. The deviations were presented to you on a Form FDA 483, List of Inspectional Observations, at the close of the inspection on January 17, 2003. FDA analyses of a sample of Duradryl Jr. ER capsules collected after the inspection revealed that this product, manufactured by your firm, is also adulterated within the meaning of Section 501(c) of the Act, in that it failed to meet dissolution specifications.

The significant cGMP observations are as follows:

1. Failure to include in laboratory records complete records of any modification of an established method employed in testing [211.194(b)].

   For example, modifications were made to the USP Dissolution Test Method procedure used for the product Diphenhydramine HCl capsules. The changes include using a medium volume of [redacted] for the 50 mg. capsules. The USP states the volume of water used for dissolution medium to be 500mL. Also, the USP dissolution tolerance limit is NLT 80% in 30 minutes, while your tolerance limit specification is [redacted] in [redacted] minutes for the 50 mg. and 25 mg. capsules. There is no documentation that identifies the reason for the modifications and no data to verify that the modifications produce results that are at least as accurate and reliable as the established USP method.

2. Failure to conduct examination and testing to assure that in-process materials conform to specifications [211.110(a)]

   For example, on numerous occasions your operators failed to document the required 30 minute weight check, during the encapsulation process of the product Diphenhydramine HCl 50 mg. capsules.

3. Failure to adequately validate cleaning procedures for equipment used in manufacturing and packaging operations of pharmaceutical products [211.67(a)].

   For example, cleaning validation was incomplete in that test methods used to analyze cleaning validation samples lacked validation at the expected concentrations and no swab recovery analysis was performed. The cleaning validation documents did not include a sampling, test method for analyzing samples, and specification limits.

4. Failure to use equipment in the manufacture, processing, packing or holding of drug products that is of appropriate design to facilitate operations for its intended use [211.63].

   For example, equipment qualification was not adequate for the following drug manufacturing equipment: Double Cone Blender [redacted] kg.), Fitzpatrick Fitzmill Comminuting Machine, Coating Pans, Kent Pony Mixer/Granulator, Double Cone Blender (20 kg.), Electronic Tablet/Capsule Counter, Strokes 16 Station

Tablet Press, Drying Room, and Shimadzu UV-Vis HPLC (LC-4), Hotpack Accelerated Stability Chamber.

5. Failure to implement an adequate testing program designed to assess the stability characteristics of drug products [211.166(a)].

   For example, the USP HPLC assay method for stability testing Acetaminophen tablet and caplet products was not validated to show it is stability indicating.

6. Failure to maintain records of the inspections of automatic, mechanical or electronic equipment, including computers or related systems. [211.68(a)].

   For example, the firm failed to maintain any background data to verify that testing of laboratory HPLC's identified as [redacted] and [redacted] had been performed or produced acceptable results. Also, written and approved protocols for testing of these HPLC's were not maintained.

7. Written records of major equipment maintenance are not included in individual equipment logs [211.182].

   Specifically, there is no system to fully document repairs to equipment used in the manufacture of pharmaceutical products. For example, in the Production Control Chart for the encapsulation of Diphenhydramine HCL 50mg capsules lot #047K2101, an operator wrote on 2/6/02 "Machine Problem Stop". On 3/6/02, an operator wrote on the Production Control Chart for Extendryl Jr. Type capsule lot #032J2301 "M/C Problem Under Repair". In both instances, there is no documentation of what caused the encapsulation process to stop or of corrective actions taken by the firm to prevent a reoccurrence.

Physical samples of your prescription drug product Duradryl Jr. ER capsules (a three component drug), lot #04G3002 were collected at [redacted] on February 27, 2003. The sample was analyzed by FDA's PHI-DO Laboratory and the dissolution results showed that two components (Chlorpheniramine maleate and Phenylephrine hydrochloride) failed to meet your firm's specification. New York Regional Laboratory confirmed the dissolution failure. We acknowledge that you have agreed to voluntarily recall and destroy the remaining product.

We have reviewed your firm's response letter dated January 30, 2003 regarding the inspectional observations made on the FDA-483 dated January 17, 2003. The written response received is inadequate. Your written response should set specific dates for corrections of each written observation and include periodic status reports detailing corrective actions for the above cGMP violations. We suggest that you thoroughly evaluate the adequacy of your procedures and controls, and that you take whatever actions are necessary to make systemic corrections and to assure that similar violations will not recur.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. The above list of deviations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Good Manufacturing Practice Regulations.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts. Failure to promptly correct these deviations may result in regulatory action without further notice. This includes seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of any additional corrective actions, including timeframes for completion with an explanation of each step being taken to prevent the recurrence of similar conditions. If corrective action cannot be completed within 15 working days, please state the reason for the delay. Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054, Attention: Andrew Ciaccia, Compliance Officer.

Very truly yours,

Douglas I. Ellsworth
District Director
New Jersey District Office

AC:slm